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EXAMINER	
SHEIKH, HUMERA N	

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1615	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	**Application No.** 10/678,922	**Applicant(s)** BALAR ET AL.	
	Examiner Humera N. Sheikh	**Art Unit** 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 13 April 2007.
2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.
3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-6 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5)☐ Claim(s) _____ is/are allowed.
6)☒ Claim(s) 1-6 is/are rejected.
7)☐ Claim(s) _____ is/are objected to.
8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.
10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a)☐ All b)☐ Some * c)☐ None of:
1.☐ Certified copies of the priority documents have been received.
2.☐ Certified copies of the priority documents have been received in Application No. _____.
3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

Receipt of the Request for Continued Examination (RCE) under 37 C.F.R §1.114 and the request for extension of time (1 month-granted), both filed 04/13/07 and the Amendment and Applicant's Arguments/Remarks, both filed 03/21/07 is acknowledged.

Applicant has overcome the following rejection(s):

(1) The 35 U.S.C. §112, first paragraph rejection of claims 1-6 has been withdrawn by virtue of the amendment deleting the term "prevention".

(2) The 35 U.S.C. §102(e) anticipation rejection of claims 1 and 3 over Shaw *et al.* (U.S. Pat. No. 6,918,869) has been withdrawn.

Claims 1-6 are pending in this action. Claims 1-6 have been amended. Claims 1-6 are rejected.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 04/13/07 has been entered.

New Matter

Claims 1-3 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants have amended the claims to recite a "stentless suture". This amendment introduces new matter into the claims. Examiner fails to find support for the term "stentless suture" as now claimed by Applicant. The term "stentless suture" has not been defined or sufficiently described in the instant specification. Examiner requests clarification as to where support can be found for the term "stentless suture".

* * * * *

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-3 recite the term "stentless suture". The claims are indefinite because it is unclear to the Examiner as to what the term "stentless suture" entails. The instant specification does not provide for a reasonable definition or description of the term.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Narayanan (US Pat. No. 6,919,100 B2) in view of Shaw *et al.* (U.S. Pat. No. 6,918,869 B2).

The instant invention is drawn to a stentless suture comprising PTFE and having a polymer coating containing releasable biological agents for the reduction of smooth muscle cell proliferation in a sutured, grafted or injured area of a vessel or arterial wall.

Narayanan ('100) discloses coated medical devices and a process for coating medical devices, used to treat a particular condition (see Abstract). The method comprises the steps of preparing an aqueous latex polymeric emulsion, adding at least one drug, agent and/or compound, in therapeutic dosages, to the aqueous latex polymeric emulsion for the treatment of a predetermined condition (col. 2, lines 56-62).

Medical devices that comprise the coatings include grafts, sutures, suture anchors and the like (col. 3, line 65 – col. 4, line 29).

Therapeutic agents that can be delivered through the coatings include paclitaxel, antibiotics (*i.e.*, dactinomycin), etc. (col. 4, line 30 – col. 5, line 16). Rapamycin is disclosed at column 9, lines 17-39. Rapamycin inhibits the proliferation of vascular smooth muscle cells in vivo. Accordingly, rapamycin may be utilized in treating intimal smooth muscle hyperplasia, restenosis and vascular occlusion in a mammal, particularly following biologically or mechanically mediated vascular injury. Rapamycin functions to inhibit smooth muscle cell proliferation and does not interfere with re-endothelialization of the vessel walls (col. 9, lines 16-28). Rapamycin also prevents T-cell proliferation when administered systemically. This is the basis for its immunosuppressive activity and its ability to prevent graft rejection (col. 9, lines 35-38). In preferred embodiments, rapamycin is incorporated onto the surface of the stent or portions thereof (col. 9, lines 51-53).

Regarding the limitation ‘plasma-assisted coating’ claimed in instant claim 2, the ‘plasma-assisted coating’ is a future-intended use limitation, which affords no patentable weight to the claims.

Narayanan does not teach that the suture/graft comprises PTFE.

Shaw ***et al.*** **(‘869)** teach a system to provide treatment of intimal hyperplasia and smooth muscle cell proliferation, which cause stenosis or restenosis of a body lumen (see column 3, lines

37-43). The system includes devices such as grafts (arterial, venous, non-vascular, vascular (col. 5, lines 36-43); (col. 7, line 62 – col. 8, line 8). Useful and suitable polymers disclosed include polypropylene (col. 8, line 29 – col. 9, line 39). Shaw *et al.* disclose that graft coverings may provide for localizing the biologically active material at the ends of a medical device. Graft coverings are strips of fabric, such as Dacron or *PTFE* that are used to hold the biologically active material in a matrix. According to Shaw *et al.,* the graft coverings are beneficial to cover the ends of a medical device to prevent abrasion of the device against the vessel wall and scar tissue (anastomic hyperplasia). Grafts may also be sutures or strips attached or interwoven into the ends of a stent, which hold the biologically active material (col. 13, lines 57-67). Suitable biologically active agents disclosed include taxol (col. 22, line 47).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the PTFE (or polypropylene) of Shaw *et al.* within the suture/grafts of Narayanan. One of ordinary skill in the art would be motivated to do so with a reasonable expectation of success because Shaw *et al* teach that graft coverings that can be utilized include PTFE to hold the biologically active material in a matrix and teach that the graft coverings are beneficial to cover the ends of a medical device to prevent abrasion of the device against the vessel wall and scar tissue (anastomic hyperplasia). The expected result would be an improved suture graft material for the effectively treating or reducing intimal hyperplasia and/or smooth muscle cell proliferation.

* * * * *

Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mollison *et al.* (US Pat. No. 6,890,546 B2) in view of Shaw *et al.* (U.S. Pat. No. 6,918,869 B2).

The instant invention is drawn to a stentless suture comprising PTFE and having a polymer coating containing releasable biological agents for the reduction of smooth muscle cell proliferation in a sutured, grafted or injured area of a vessel or arterial wall.

Mollison *et al.* ('546) teach a medical device comprising a supporting structure having a coating on the surface thereof, the coating containing a therapeutic substance, as a drug. Supporting structures for the medical devices include arterio-venous grafts and by-pass grafts (see Abstract); (col. 4, lines 57-65).

Mollison *et al.* also teach a method of treating a variety of disease states, including restenosis, post-transplant tissue rejection, immune and autoimmune dysfunction, fungal growth and cancer (col. 4, lines 53-56).

More particularly, the invention relates to semisynthetic analogs of rapamycin, means for their preparation, pharmaceutical compositions containing such compounds and methods of treatment employing the same (col. 1, lines 15-22).

Coatings suitable for use in the invention include polymeric coatings that can comprise any polymeric material in which the therapeutic agent is substantially soluble. The coating can be hydrophilic, hydrophobic, biodegradable or non-biodegradable. This medical device reduces restenosis in vasculature (col. 6, lines 40-49).

Hyperproliferative vascular diseases that can be treated include smooth muscle cell hyperplasia, restenosis and vascular occlusion, particularly following biologically- or mechanically-mediated vascular injury (col. 11, lines 48-53). Additionally, compounds of the invention possess FK-506 antagonistic properties. The compounds of the invention may be used to treat disorders involving immunodepression, including AIDS, cancer, fungal infections and trauma (including wound healing, surgery and shock) (col. 13, line 62 – col. 14, line 29).

In addition to stents, other devices used to introduce drugs to the vasculature include *grafts*, catheters and balloons (col. 11, lines 64-66).

According to Mollison *et al.*, the coating can comprise any polymeric material. The purpose of the coating is to serve as a controlled release vehicle for the therapeutic agent or as a reservoir for a therapeutic agent to be delivered at the site of a lesion (col. 12, lines 2-7).

Regarding the limitation 'plasma-assisted coating' claimed in instant claim 2, the 'plasma-assisted coating' is a future-intended use limitation, which affords no patentable weight to the claims.

Mollison *et al.* do not teach PTFE.

Shaw *et al.* ('869) teach a system to provide treatment of intimal hyperplasia and smooth muscle cell proliferation, which cause stenosis or restenosis of a body lumen (see column 3, lines 37-43). The system includes devices such as grafts (arterial, venous, non-vascular, vascular (col. 5, lines 36-43); (col. 7, line 62 – col. 8, line 8). Useful and suitable polymers disclosed include polypropylene (col. 8, line 29 – col. 9, line 39). Shaw *et al.* disclose that graft coverings may provide for localizing the biologically active material at the ends of a medical device. Graft coverings are strips of fabric, such as Dacron or *PTFE* that are used to hold the biologically active material in a matrix. According to Shaw *et al.,* the graft coverings are beneficial to cover the ends of a medical device to prevent abrasion of the device against the vessel wall and scar tissue (anastomic hyperplasia). Grafts may also be sutures or strips attached or interwoven into the ends of a stent, which hold the biologically active material (col. 13, lines 57-67). Suitable biologically active agents disclosed include taxol (col. 22, line 47).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the PTFE (or polypropylene) of Shaw *et al.* within the graft sytems of Mollison *et al.* One of ordinary skill in the art would be motivated to do so with a reasonable expectation of success because Shaw *et al* teach that graft coverings that can be utilized include PTFE to hold the biologically active material in a matrix and teach that the graft coverings are beneficial to cover the ends of a medical device to prevent abrasion of the device against the vessel wall and scar tissue (anastomic hyperplasia). The expected result would be a highly effective graft material for the treatment or reduction of intimal hyperplasia and/or smooth muscle cell proliferation, as similarly desired by Applicant(s).

Response to Arguments

Applicant's arguments filed 03/21/07 have been fully considered and were found partially persuasive.

- **35 U.S.C. §112, 1st paragraph rejection:**

Applicant argued, "Independent claims 1 and 4 have been amended to recite "reduction" without "prevention".

Applicant's arguments have been considered and were found persuasive. The 35 U.S.C. §112, first paragraph rejection of claims 1-6 has been withdrawn by virtue of the amendment deleting the term "prevention".

- **35 U.S.C. §102(e) rejection of Claims 1 and 3 over Shaw et al. (6,918,869):**

Applicant argued, "Shaw et al. disclose "an implantable medical device which has two opposing ends, each having a surface, and a middle portion and a surface" (col. 3, lines 63 - 65). Such devices include but are not limited to catheters, guide wires, ballons, filters, stents, stent grafts, a commercial synthetic graft, prosthetic seed, dialysis shunt, aneurysm coil, a biological vascular or non-vascular graft, filters, implants, and angioplasty devices (col. 8, lines 3 - 8). As the Examiner points out, SHAW et al. disclose that a 'graft may be sutures of strips attached to or interwoven into the ends of the stent, which hold the biologically active material" (col. 13, line 65 - 67). SHAW et al. use the sutures as a part of a larger combination with a stent, but fail to disclose a PTFE coated suture without it being part of a combination with a stent. Independent claim 1 and dependent claim 3 have been amended to recite only a stentless suture, rather than a "suture, graft, and suture/graft combination."' Since SHAW et al. do not teach each and every element of Applicants' invention, Applicants respectfully request that the Examiner withdraw the rejection under 35 U.S.C. 102(e) based on SHAW et al. "

Applicant's arguments have been considered and were found persuasive. The 35 U.S.C. §102(e) rejection of claims 1 and 3 over Shaw ('869) has been withdrawn.

- **35 U.S.C. §103(a) rejection of Claims 1-6 over Narayan (6,919,100) in view of Shaw et al. (6,918,869):**

Applicant argued, "NARAYANAN discloses implantable medical devices, which may be coated to minimize or substantially eliminate a biological organism's reaction to the introduction of the medical device to the organism or to treat a particular condition. The Examiner contends that it would be obvious to combine the PTFE of SHAW et al. with the device of NARAYANAN. SHAW et al. disclose, as the Examiner points out, the use of PTFE as a graft covering (col. 13, lines 58 - 61). NARAYANAN discloses '~...implantable medical devices, [which] may be coated..." (abstract). NARAYANAN discloses devices such as "surgical devices, sutures, staples, anastomosis devices, vertebral disks, bone pins, suture anchors, hemostatic barriers, clamps, screws, plates, clips, vascular implants, tissue adhesives and sealants, tissue scaffolds, various types of dressings, bone substitutes, intraluminal devices, and vascular supports..." (col. 4, lines 19 - 24). Both the NARAYANAN and SHAW et al. patents issued from disclosures filed between December 2002 and January 2003. Considering the close filing dates, the inventors from both references probably developed what they disclosed in their patents at approximately the same time. Therefore, if Applicants' invention was obvious, the inventors on each of the patents should have seen at that time that they could use PTFE on sutures in the way Applicants' invention teaches. Because it was NOT obvious, neither patent contains the invention Applicants now claim. There can be no reasonable expectation of success in making Applicants' invention based on the NARAYANAN and SHAW et al. references since one would wonder why no person on each disclosure discovered Applicants' invention. Therefore, Applicants respectfully request that the Examiner withdraw the rejection of claims 1 - 6 under 35 U.S.C. 103(a) as being unpatentable over NARAYANAN in view of SHAW et al."

Applicant's arguments have been considered, but were not found persuasive. Applicant has not established how the PTFE sutures disclosed by the prior art are distinct to the PTFE suture claimed in the instant invention. The claims as currently presented do not sufficiently define over the explicit teachings of the prior art of record.

- **35 U.S.C. §103(a) rejection of Claims 1-6 over Mollison et al. (6,890,546) in view of Shaw et al. (6,918,869):**

Applicant argued, "MOLLISON et al. disclose "[a] medical device comprising a supporting structure having a coating on the surface thereof, the coating containing a therapeutic substance, such as, for example, a drug" (abstract). The Examiner contends that it would be obvious to combine the PTFE of SHAW et al. with the graft system of MOLLISON et al. MOLLISON et al. disclose devices such as "coronary stents, peripheral stents, catheters, arterio-venous grafts, by-pass grafts, and drug delivery balloons used in the vasculature" (abstract). MOLLISON et al. fail to disclose a suture. Applicants' amended claims 1 - 6 all recite a suture. Neither MOLLISON et al. nor SHAW et al. teach or suggest a suture at all. Therefore, combining the references would still not provide a person with Applicants' entire invention. In addition, there is no motivation, suggestion or teaching to combine SHAW et al. and MOLLISON et al. "To establish obviousness based on a combination of the elements disclosed in the prior art, there must be some motivation, suggestion or teaching of the desirability of making the specific combination that was made by the applicant." In re Kotzab, 217 F.3d 1365, 1370 (Fed. Cir. 2000). Failure to disclose a suture in the MOLLISION et al. reference means there would be no motivation, suggestion, or teaching to combine the reference with SHAW et al. It would require an enormous amount of experimentation to determine whether PTFE Would work with a suture when MOLLISON at al. fail to disclose a suture. Therefore, contrary to the Examiner's opinion, there would not be a reasonable likelihood of success in producing a PTFE coated suture like that of Applicants' Therefore, Applicants respectfully request that the Examiner withdraw the rejection of claims 1 - 6 under 35 U.S.C. ~103(a) as being unpatentable over MOLLISON et al. in view of SHAW et al.

Applicant's arguments have been considered, but were not found persuasive. Applicant's argument that "neither Mollison nor Shaw recite a suture" was not persuasive since Shaw explicitly teaches grafts that may be sutures attached or interwoven into the ends of the stent, which hold the biologically active material (see col. 13, lines 57-67). Moreover, Shaw expressly teach graft coverings comprised of PTFE or polypropylene material.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, ample motivation has been provided by the prior art teachings. While Mollison does not teach PTFE, Shaw et al. was relied upon for remedying this deficiency of Mollison by their teaching of useful and suitable polymers such as PTFE or polypropylene (col. 8, line 29 – col. 9, line 39).

It remains the position of the Examiner that Applicant has not demonstrated a sufficient showing of any unexpected or superior results attributed by the 'stentless suture' of the invention. The claims, at present, remain broad enough to read over the explicit teachings of the prior art. Applicant has not provided how their sutures would distinguish over the sutures disclosed by the art.

Applicant argued, "Applicants have complied with the requirements of the statute. In particular, in addition to the written description and best mode requirements, Applicants provide an enablinq disclosure for a stentless suture comprising PTFE and having a plasma assisted coating deposited on the suture containing releasable biological agents for the reduction of intimal hyperplasia, smooth muscle cell proliferation in a sutured, grafted, or injured area of a vessel or arterial wall. Applicants disclosed in their patent application that their invention uses plasma assisted coatings to provide complex delivery strategies (p. 12, lines 8 - i0). Applicants have adopted the use of plasma assisted coatings in their invention, and provided an enabling disclosure to support it. Therefore, Applicants respectfully request that the Examiner withdraw the contention that claim 2 is a future intended use limitation."

These arguments were not persuasive. The term 'plasma-assisted coating' is a relative, rather vague term, which has not been sufficiently defined. Nonetheless, the prior art teaches similar suture/graft therapeutic devices for local drug delivery comprising similar components as claimed by Applicant. Moreover, the devices of the prior art are also intended for the same objective and field of endeavor as that desired by Applicants, namely, reduction of intimal hyperplasia and smooth muscle cell proliferation.

Absent a showing of unexpected results, the instant invention would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, based on the disclosure of the cited art delineated above.

Conclusion

-- No claims are allowed at this time.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday through Friday during regular business hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Art Unit 1615

June 23, 2007

HUMERA N SHEIKH
PRIMARY EXAMINER
TC-1600

hns